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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/580,462 05/26/00 HEINEMANN S SALK1590-3

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EXAMINER

ULM, J

ART UNIT	PAPER NUMBER
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1646

DATE MAILED:

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/580,462

Applicant(s)
Heinemann et al.

Examiner
John Ulm

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 2, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11, 12, and 14-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9, 11, 12, and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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1) Claims 5 to 9, 11, 12 and 14 to 17 are pending in the instant application.

2) The figures in the instant application clearly fail to meet the requirements of 37 C.F.R. § 1.84(U)(1), which states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly. Correction is required.

3) Claims 5 to 9, 11, 12 and 14 to 17 stand objected to because they recite an improper Markush Group for those reasons of record in section 2 of Paper Number 3. The four receptor subunits recited therein do not have unity of invention because they do not share a common utility which is based upon a shared structural feature which is disclosed as the basis for that common utility and which is lacking from the prior art. Nicotinic acetylcholine receptor subunits were known in the art prior to the time of the instant invention. Therefore, correction is required.

4) Claims 5 to 9, 11, 12 and 14 to 17, in so far as they are drawn to an isolated nucleic acid encoding other than a neuronal nicotinic receptor beta2 subunit, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected , there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5. Applicant has traversed this rejection on the premise that the four

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subunits recited in these claims share the common utility of being employable in binding assays. This argument is not persuasive because this utility is not unique to the four receptor subunits recited in the claims. Virtually any protein can be employed in an assay to identify compounds which can bind thereto.

The requirement is still deemed proper and is therefore made FINAL.

5) Claims 11, 12 and 16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. See M.P.E.P. 608.01(n)III.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6) Claims 5, 8, 9 and 11 to 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not provide a written description of an isolated nucleic acid encoding a beta2 neuronal nicotinic acetylcholine receptor subunit having other than the amino acid sequence presented in Figure 7B of the instant

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application. In the decision of *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997), the court held that:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.' *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, 'an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.' *Id.* at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of a single isolated DNA encoding a particular neuronal nicotinic acetylcholine receptor subunit identified therein as beta2 and having very specific physical and structural properties, the instant specification does not provide a structural formula which is definitive of all proteins which might be encompassed by the

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term “neuronal nicotinic acetylcholine receptor beta2 subunit”. Further, the instant specification does not provide a written description of a nucleic acid which can hybridize to that single disclosed nucleic acid or which has “substantial sequence homology” thereto.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 to 9, 11, 12 and 14 to 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7) Claims 5 to 9, 11, 12 and 14 to 17 are vague and indefinite in reference to the term “beta2”. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a “beta2” subunit an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. The definition provided for this term on page 14 of the instant specification illustrates the ambiguity of this term. As stated therein “beta2 refers to a gene encoding a neuronal nicotinic acetylcholine receptor non-agonist binding subunit of the same name”.

8) Claims 8 and 9 are vague and indefinite because they recite the limitation “functionally equivalent” without identifying those functions whose presence are being required.

9) Claim 11 is vague and indefinite because the metes and bounds of the limitation “having substantial sequence homology” are undeterminable. The definition for this term which is

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provided in the first paragraph on page 15 of the instant specification is as vague as the term itself because the definition repeatedly employs the vague and indefinite term "substantially the same" to define this limitation.

10) Claim 15 is vague and indefinite because the limitation "under stringent conditions" is conditional and no specific conditions are recited in either the claims or the specification.

11) Claim 16 is vague and indefinite because there is no antecedent basis for "the nucleic acid of claim 7", which is drawn to "pure DNA sequences".

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12) Claims 7 to 9, 11 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "DNA sequence" is a property of a nucleic acid and not a material entity in and of itself. Properties such as shapes, sizes, colors and sequences are not subject to patentability.

13) Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This claim encompasses an mRNA molecule as it occurs in nature.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

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Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306.
Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800